

12/19/03

K031373

Section P: 510(k) Summary
iXL™ Diabetes Management System

Submitter: Insulet Corporation
100 Cummings Center
Suite 239G
Beverly, MA 01915

Contact: A. Arthur Rankis
Director of Quality and Regulatory Affairs
978-299-0203

Device Name: iXL™ Diabetes Management System

Predicate Devices:

The iXL Diabetes Management System is substantially equivalent to the Medtronic MiniMed® System, consisting of the 508 Insulin Pump, Reservoir, Sil-serter Infusion Set Insertion System, and the Silhouette Infusion Set.

Intended Use:

The iXL™ Diabetes Management System is intended for continuous, subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin.

Description of the iXL™ Diabetes Management System

The iXL Diabetes Management System has two (2) components: a Remote Controller, and an insulin infusion Pump, and two accessories; a fill syringe, and fill needle.

The Remote Controller is a hand held, battery-operated device, with 9 functional buttons and an electro-luminescent (EL) backlit liquid crystal display (LCD). The device provides audio alarms, alerts and reminders.

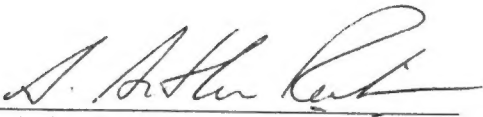
The Pump is activated and controlled exclusively through the use of the Remote Controller. The Pump and Remote Controller interact wirelessly using secure, radio frequency (RF).

The Pump is a microprocessor controlled device. The Pump is worn directly on the body in the same manner and general locations as a conventional insulin infusion set. The Pump will deliver insulin based on the users custom programmed basal rate and bolus doses for up to 72 hours. The Pump provides audio alarms, alerts and reminders.

Comparison of the New Device to the Predicate Devices

The iXL Diabetes Management System is substantially equivalent to the commercially available (predicate) Medtronic MiniMed System, consisting of the 508 Insulin Pump, the Sil-Serter infusion set insertion system, the Silhouette infusion set and Reservoir. Both systems are portable, external insulin infusion devices that deliver insulin from a syringe style reservoir and include a remote controller.

The difference between the systems is the arrangement of the elements. The user interface on the iXL Diabetes Management System has been moved from the Pump to the Remote Controller, and the insertion system and infusion set have been integrated into the Pump.



A. Arthur Rankis
Director of Quality and Regulatory Affairs
Insulet Corporation

December 18, 2003

Date

CONFIDENTIAL



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 19 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Insulet Corporation
C/O Mr. A. Arthur Rankis
Director of Quality and Regulatory Affairs
100 Cummings Center
Suite 239G
Beverly, Massachusetts 01915

Re: K031373

Trade/Device Name: iXL Diabetes Management System
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: September 24, 2003
Received: September 25, 2003

Dear Mr. Rankis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

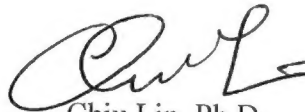
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number
(if known)

Device Name iXL™ Diabetes Management System

Indications for Use For the continuous, subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

Rafaela Ciccarone
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: 1031373